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Industrial Pharmacy and its use of Drug Discovery Process Innovations

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DESCRIPTION

Chemometric models and Quality by Design (QbD) are two sides of the same coin. While QbD models use experimentally designed settings to optimize some quality attributes, these settings can also be used to predict the same attributes chemo metrically. The goal was to synchronise the optimization of comparative dissolution results of carvedilol immediate release tablets with Chemometric prediction of the product's dissolution profile and content uniformity. As an industrial application, variables for optimization were chosen through risk assessment using archived product records at the pharmaceutical site. The sucrose, sodium starch glycolate, lactose monohydrate, and avicel Ph 101 contents of the experimental tablets were varied in 20 different ways. To determine the design space, the excipient contents were modelled in HCL, acetate, and USP dissolution media using the F1 dissimilarity factor and the F2 similarity factor. We used Partial Least Squares based Structural Equation Modelling (PLS-SEM) to investigate how excipients and their NIR records explained product dissolution. Finally, the optimized formula was used with varying carvedilol content for Chemometric prediction of content uniformity. Data-driven solutions have been widely used over the last two decades. These solutions are widely used in many fields, including the pharmaceutical industry, healthcare, food, and agriculture. Each field is constantly on the lookout for a low-cost source of data that can be processed using advanced analytics to produce valuable and expensive information. The use of non-destructive spectral techniques in conjunction with multi-variate calibration models has delivered potential benefits to the pharmaceutical industry. The pharmaceutical industry employs data-driven solutions in both the R&D and routine manufacturing phases. In the R&D phase, the FDA currently supports the use of improved development approaches such as Quality by Design (QbD). It also supports the use of Process Analytical Technology (PAT) and multi-variate calibration models as tools to support continuous manufacturing. Regulatory bodies are developing standards and controls for this conceptual shift in pharmaceutical development and manufacturing, but deficiencies in process monitoring and data collection continue to limit their use. As a result, the guidelines require risk assessments to be included in order to verify how deficiencies in process monitoring and data collection affect product quality. Pharmaceutical 3D printing represents a potentially new dosing and manufacturing approach for the pharmaceutical industry, with unprecedented opportunities for dosage strength personalization. Fused Deposition

Modelling (FDM) is a 3D printing technique that offers benefits for decentralized on-site manufacturing in hospitals and pharmacies. This study introduces industrially relevant formulations for filaments with the required mechanical properties to be 3D-printable, as well as providing immediate release (IR) dosage forms using safe materials approved for paediatrics use. As a hydrophilic polymer, hydroxypropyl-cellulose (HPC) SSL was chosen, and caffeine with a load of 5-20% was chosen as a thermally stable model drug. Additional water-soluble polymers tested in combination with HPC and xylitol were poly-(vinyl pyrrolidone-vinyl acetate) copolymer (Kollidon VA64) and poly-(vinyl alcohol-polyethylene glycol) graft copolymer (Kollicoat IR). PEG4000 and maltodextrin were evaluated as hydrophilic plasticizers and PEG4000 and maltodextrin as Hot-melt extruded formulations were 3D-printed into honeycomb geometry solid dosage forms with high (100%) and low (80%) infill density using a scalable twin-screw extruder. The formulation and tablet design parameters were used to achieve rapid or very rapid release. Independent of infill density, PEG4000 in combination with Kollidon VA64 demonstrated superior processability and significantly accelerated matrix release properties. Caffeine content reduction improved hot-melt extrusion processability for each formulation but increased dissolution time. Kollicoat IR produced superior mechanical properties in the manufactured filaments, as well as ease of handling and successful 3D printing for drug loads ranging from 5 to 20%. Lowering the infill density of 3D-printed tablets resulted in faster drug dissolution for the majority of formulations, as expected from the literature. However, the extent of the infill density effect varied depending on formulation. Caffeine was discovered in a stable crystalline state in 3D-printed tablets. Drug dissolution in vitro appeared to be temperature dependent. This broad excipient investigation is the first step in developing a toolbox approach to FDM processability in conjunction with the immediate release characteristics of personalised dosage forms.